PGI48

HEALTH-RELATED QUALITY OF LIFE, WORK PRODUCTIVITY, AND DAILY ACTIVITY AMONG A SAMPLE OF COMMERCIALLY INSURED PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION OR CHRONIC CONSTIPATION IN THE UNITED STATES

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OBJECTIVES: To assess the impact of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC) on health-related quality of life (HRQOL), work and daily activity among US commercially-insured patients. **METHODS:** Consenting survey-eligible patients ≥18 years identified from the HealthCore Integrated Research Database completed a cross-sectional survey. IBS-C cases that had ≥1 IBS claim and either ≥2 constipation claims or ≥1 constipation claim and ≥1 constipation-related pharmacy claim and CC cases that had ≥2 constipation claims ≥90 days apart or ≥1 constipation claim and ≥1 constipation-related pharmacy claim ≥90 days apart were included. Controls were matched on age, gender, region, plan type and insurance status. Only cases meeting and controls not meeting modified Rome III criteria completed the survey. Short Form-12 v2 physical component summary (PCS) and mental component summary (MCS) [range: 0–100; US normative mean=50]) and EuroQol-5D (EQ-5D; range: 0=death to 1=perfect health) assessed HRQOL. Work Productivity and Activity Impairment Questionnaire (General Health version) assessed absenteeism, presenteeism and daily activities (higher percentages indicate greater impairment). Indirect costs were calculated based on overall work productivity loss (absenteeism+presenteeism) using the human capital method. **RESULTS:** Among 354 respondents (177 IBS-C/CC cases, 177 controls; mean age 46±15 years; 86% female; 66% employed), mean PCS and MCS scores were lower for cases versus controls (mean differences: 8.9 ($p<0.01$), 6.8 ($p<0.01$), respectively). EQ-5D mean utility score was lower among cases versus controls (0.7 versus 0.9; $p<0.01$). Cases also had greater overall work productivity loss (28% versus 12%; $p<0.01$) and activity impairment (39% versus 15%; $p<0.01$). Estimated indirect costs were $108 higher per employed respondent/week for cases versus controls ($p<0.01$). **CONCLUSIONS:** IBS-C/CC patients reported lower HRQOL and greater impairments in work and daily activity compared with matched controls. Treatments that effectively manage IBS-C/CC symptoms may improve these outcomes in IBS-C/CC patients.

PGI49

MODELS OF THE IMPACT OF MAJOR LIVER DISEASES ON EQ-5D VISUAL ANALOGUE SCALE AND UTILITY-INDEX: CONVERGENCES AND DIVERGENCES

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OBJECTIVES: Liver diseases (LDs) can reduce health-related quality-of-life (HRQoL), with an important impact on the burden of LDs. Our aim was to analyze the impact of the major LDs on EQ-5D Visual Analogue Scale (VAS) and utility-index (UI) through different regression models, using HRQoL of the general population as a reference. **METHODS:** HRQoL data were measured using the EQ-5D-3L in a sample of patients with 9 major LDs enrolled during 2011-2012 in a multicenter study conducted in the most populated region of Italy, Lombardy. Such data were added to those recorded in 2013 on a representative sample of Lombardy general population. Relationships between the outcomes of interest (VAS and UI) and LDs were explored through ordinary least squares (OLS) and Tobit regression, that accounts for ceiling effect, adjusting for age and gender. Goodness-of-fit was assessed through R2 (OLS) and pseudo-R2(Tobit). **RESULTS:** The sample included 9,817 subjects (3,017 with LDs). OLS and Tobit regressions performed similarly on VAS (R2:0.13,pseudo-R2:0.12) and estimated the largest and significant HRQoL reduction in patients with decompensated cirrhosis (DC), followed by those with autoimmune hepatitis (AIH) and hepatocellular carcinoma (HCC). As for UI, the Tobit model performed better than OLS regression (R2:0.11,pseudo-R2:0.15), with the highest decrease estimated in patients with DC, followed by those with HCC and compensated cirrhosis. **CONCLUSIONS:** The Tobit model performed slightly better than OLS regression on the UI, but not on VAS, maybe due to a stronger ceiling effect in UI. This distributional difference mirrors different data-generation mechanisms: UI is derived from the EQ-5D-3L domains, while VAS is reported by patients. Therefore, VAS and UI might capture different aspects of HRQoL, as supported by our results, that show how the same LD can be differently associated with VAS and UI (e.g.: AIH seemed to have an impact on VAS only, while HCC on UI only).

PGI50

LIFE QUALITY OF YOUNG ADULT PATIENTS WITH INFLAMMABLE BOWEL DISEASE

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OBJECTIVES: The number of patients over 19 years with registered inflammable bowel disease which has non-infectious origin is duplicated in the last 16 years (KSH 2013). Our aim is to get a picture about the different dimensions of life quality in the course of the chronic disease. **METHODS:** Cross-sectional, quantitative examination was carried out between 15.07.2014 and 31.12.2014 at the Clinical Centre of the University of Pécs. Patients with M Crohn and ulcerative colitis between the age of 18 and 46 were selected with non-randomized, convenience sampling method. For data collection we used standard questionnaires (Illness Intrusiveness Rating Scale, IBDQ, Coloplast life quality questionnaire) and questions about demographic data (N=103). We used Microsoft Excel 2013 software to carry out descriptive statistics, two-sample t-test and $\chi 2$- test ($p<0.05$). **RESULTS:** The age of the patients were between 31.03±8.18. Illness Intrusiveness Rating Scale (the effect of the disease on role efficiency) was evaluated more unfavourable by the patients with ulcerative colitis ($p<0.05$). Average life quality is not affected by gender ($p=0.21$), marital status ($p=0.15$), te type of the disease ($p=0.77$), and employment status ($p=0.75$). Patients with stoma evaluated their life quality only with 42.33 points from the overall 80. **CONCLUSIONS:** Patients with intestinal diseases are defatigable, and have abdominal problems frequently. In case of ulcerative colitis the burden of disease is higher, life quality is less favourable. Stoma negatively affects life quality. The residence is significantly affected by the disease burden and quality of life.

PGI51

THE DEMOGRAPHIC ASPECTS OF TURKISH CHRONIC HEPATITIS C PATIENTS AND THE TREATMENT INITIATION FROM A PHYSICIAN'S & PATIENT'S POINT OF VIEW. FIRST INTERIM ANALYSIS OF TURKISH DATA FROM MOSAIC STUDY (AN INTERNATIONAL MULTICENTER PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE EPIDEMIOLOGY, HUMANISTIC AND ECONOMIC OUTCOMES OFTREATMENT FOR CHRONIC HEPATITIS C VIRUS)

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OBJECTIVES: Chronic Hepatitis C Virus (HCV) infection negatively impacts the patient's quality of life. Interferon (IFN) based therapy has been the standard of care for many years yet antiviral therapy of HCV has rapidly evolved since the introduction of direct acting antivirals (DAA). This report is based on Turkish Mosaic Study. The objective is to characterize patients with chronic HCV and assess the impact of IFN-containing treatment on health related quality of life, work related productivity and activities of daily living and health care utilization. **METHODS:** MOSAIC is an international prospective multicenter observational study that is conducted in 20 countries. Consecutive patients with chronic HCV who initiated an IFN based treatment within 12 weeks were followed for 48 weeks. Patient characteristics, co-morbidities, treatment history, HCV genotype and clinical status were recorded. The response type recorded for previous treatment as null response, relapse, discontinued and partial response. **RESULTS:** Ninety one of 152 patients were treatment naïve, and the 61 were treatment experienced. Relapse was the dominating response type (50%). GT1 patient ratio was 65,8%, non GT1 patient was 5,9%, and 28% of patients were unknown at the date of the report. 42.8% of patients were male, the mean age was 55.1 . The physicians have not recommended treatment for 73.6% of patiens, and 16.4% of patients rejected the treatment. The leading reasons for physicians and the patients were "waiting for IFN-free treatment option" is followed by "presumed tolerabilty issue". **CONCLUSIONS:** IFN based therapy has been the standard of care for CHC infection for many years yet the antiviral treatment paradigm of HCV has rapidly evolved since the introduction of IFN-free direct acting antivirals. Higher efficacy with less side effects seems to improving the standard of care.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI52

DIAGNOSIS AND MANAGEMENT OF MODERATE-TO-SEVERE IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) IN GERMANY: RESULTS FROM THE IBIS-C STUDY

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OBJECTIVES: This is the first study to assess the diagnostic and therapeutic management of moderate-to-severe IBS-C in six European countries (France, Germany, Italy, Spain, Sweden and UK). Here we present the diagnosis and management results from Germany. **METHODS:** Observational 12-month study (6 months retrospective and 6 months prospective) in patients diagnosed with IBS-C (Rome-III criteria) in the last five years and moderate-to-severe disease severity at inclusion (IBS-Symptom Severity Scale (IBS-SSS) score ≥175). One of the main objectives was to determine healthcare resource utilisation (HRU) and costs prior to and after an active phase of the disease. **RESULTS:** 102 patients were included (43% severe, mean age [±SD] 47.6±18.1 years old, 83.3% female). Mean time since diagnosis: 4.6±8.4 years; mean symptom duration: 15.0±16.9 years. Diagnostic procedures since the onset of symptoms were highly variable: the most common were colonoscopies(78.4%), blood tests (65.7%), and abdominal ultrasounds(62.7%). The main associated comorbidities were insomnia(31.4%), hypertension(28.4%), chronic pain (27.5%), depression(27.5%), and gastroesophageal reflux disease (GERD; 27.5%). 66.7% of patients had an average of 4.0±2.5 diagnostic tests during follow-up and 71.6% took prescription drugs (54.9% for IBS-C). The most common medication groups were laxatives (35.6%), prokinetics (23.3%), antispasmodics (15.1%), and analgesics (11.0%). Overall, 69.6% of patients took non-prescription drugs for their IBS-C (32.4% laxatives and 19.6% herbal medicine) and 27.5% of patients sought complementary therapies. Overall, improvement in symptom severity (IBS-SSS total score±SD) was observed between baseline (288.3±78.8) and the 6-month visit (228.1±9.1). **CONCLUSIONS:** Patients with moderate-to-severe IBS-C often remain undiagnosed for over 10 years and undergo a variety of diagnostic procedures. Chronic comorbidities are frequent. Despite a high use of both prescription and non-prescription drugs, mean symptom severity did improve but remained "moderate" overall.

PGI53

CLINICAL CHARACTERISTICS AND PATTERNS OF CARE AMONG PATIENTS WITH GENOTYPE 1 (G1) HEPATITIS C VIRUS IN EUROPE (EU)

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OBJECTIVES: Assess clinical characteristics and patterns of care among patients with G1 Hepatitis C virus (HCV) in EU. **METHODS:** A multi-center retrospective chart-review study of HCV patients was conducted in the EU (France/Germany/Italy/Spain/UK) in 4Q2014 to collect de-identified data on diagnosis, clinical

status, and treatment patterns. Physicians were screened for duration of practice (≥3yrs) and patient volume (≥15 HCV patients/mo) and recruited from a large panel to be geographically representative. Medical charts of the next 10 consecutive HCV patients were abstracted. G1 HCV patient data was analyzed. **RESULTS:** 2067 eligible G1 HCV patients were included in the analysis (France:374/Germany:506/Italy:412/Spain:475/UK:300). Patient characteristics included (France/Germany/Italy/Spain/UK) - mean age (yrs):53/49/55/52/45; male: 61%/67%/61%/59%/69%; patient weight <=80kg:81%/66%/83%/74%/76%; majority were G1-subtype A (52%/44%/31%/34%/68%) or B (48%/54%/68%/66%/32%); any substance-abuse:23%/18%/10%/17%/47%; route of infection via intravenous drug use:55%/33%/31%/41%/69%, via blood transfusion:19%/26%/21%/36%/7%, via heterosexual contact:5%/11%/22%/11%/7%, via homosexual contact:8%/13%/10%/6%/12%; current fibrosis scores were – F0:9%/18%/6%/7%/20%, F1:18%/30%/25%/25%/32%, F2:24%/28%/32%/24%/18%, F3:21%/17%/17%/20%/11%, F4:29%/6%/20%/23%/19%. In France/Germany/Italy/Spain/UK, latest mean alanine aminotransferase levels were:58/90/95/62/73; patients with undetectable (0-500) viral load (VL):5%/2%/25%/2%/1%; 501-<=1Million VL-count:58%/39%/52%/75%; >1M VL-count:38%/26%/38%/45%/25%. Treatment patterns included (France/Germany/Italy/Spain/UK)- currently treated:23%/28%/20%/17%/20%, not currently treated (previous treatment non-responder, discontinued or relapsed, or therapy complete and awaiting sustained viral response):21%/20%/29%/30%/22%, not current treated because patient achieved sustained viral response:19%/12%/11%/13%/6%; treatment naïve/never been treated:38%/40%/41%/41%/52%. **CONCLUSIONS:** In this cohort of G1 HCV patients, treatment rates and disease burden varied among studied countries in EU; only a small proportion of patients had undetectable VL or was not treated owing to achieving sustained viral response. Further research is warranted to assess the observed treatment patterns, effectiveness of regimens, and patient management strategies to alleviate patient burden.

PGI54

PROTON PUMP INHIBITORS IN ITALY: IT'S TIME TO MAKE A (POLICY) CHANGE

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OBJECTIVES: The analysis aimed to evaluate the evolution of the national and regional public expenditure regarding Proton Pump Inhibitors (PPIs) in Italy, in relation to national and regional policies. **METHODS:** The analysis combined data published by the Italian Medicines Agency (AIFA) and Regions and regional and national laws, to understand the impact of the applied policies on PPIs expenditure. **RESULTS:** Over the past ten years, PPIs consumption increased by 280% (around 14% yearly), with lansoprazole reaching +533%. The number of patients ≥ 18 treatable with PPIs in 2013 was 2.873.500 (6% of adult population), being the first class in terms of expenditure with a per capita value of 15.2€ and consumptions of 74 DDD/1.000 inh./die. Consumptions and expenditure incresed by respectively 6.5% and 1.6% vs 2012. AIFA also highlighted a trend to prescriptive inappropiateness over the years, where the 46.5% of patients do not meet the reimbursability criteria by law. At regional level, Regions have issued a number of regional laws to contain both consumptions and expenditure (e.g. through reference pricing or guidelines to encourage the prescription of genericated drugs), identifying specific performance indicators and target values. We estimated potential savings from the correct application of the reimburability criteria amounting to 260 million €/year, if Regions were able to control prescriptive appropriateness, to which additional savings could be added through focused cost-containment measures. **CONCLUSIONS:** Despite a number of efforts at both central and regional level, the trend towards inappropriateness and expenditure increase of PPIs is confirmed. A review of both national and regional policies on PPIs expenditure is key to reduce the current waste of economic resources and, with a stable total budget, guarantee additional funding for innovation.

PGI55

ASSESSING THE RATIONALITY OF COSTS OF DRUG TREATMENT OF NONALCOHOLIC STEATOHEPATITIS IN THE HOSPITAL OF UKRAINE

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OBJECTIVES: Comprehensive assessment of the financial costs of drug treatment of nonalcoholic steatohepatitis (NASH) in a hospital of Kharkiv, Ukraine. **METHODS:** For the study, the schemes medicinal histories of 54 patients with NASH in a hospital in Kharkov during 2013 were used. The structure of costs of NASH treatment was assessed by the ABC analysis. Assessment of the level of NASH treatment correspondence was conducted by the formal VEN analysis according to the National Drug Formulary (NDF) of Ukraine (2013). Index "V" was put in case of availability of the drug in the NDF, index "N" – in case of its absence. Directions of NASH treatment were assessed by the prescriptions of drugs according to requirements of Ukrainian Cinical Guidelines (O.Ia. Babak, 2007) and according to Practice Guideline by the American Association for the Study of Liver Diseases (AASLD) for 2012. In determining the cost of drugs, their prices as of May 2015 by the data of Morion reference and retrieval system "Drugs" were used. **RESULTS:** Drug treatment of patients with NASH by pharmacotherapeutic groups met the basic requirements of Ukrainian Clinical Guidelines and Guidelines of American scientists AASLD, which confirms the rationality of prescriptions. According to the ABC/VEN analysis, most of the funds for treatment (82%) were spent on 76% of drugs included in the NDF. But 24% of drugs were missing from the NDF of Ukraine, indicating the need to correct NASH treatment in the hospital of Ukraine. **CONCLUSIONS:** 76% of drugs prescribed to patients with NASH can be considered rational, but 24% of drugs had index "N", indicating their inappropriate use. Comparison of the ABC and VEN analysis showed the need to correct NASH treatment in the hospital of Ukraine, as 18% of funds were spent on minor drugs which are not represented the NDF of Ukraine.

PGI56

THE BURDEN OF MODERATE-TO-SEVERE IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) IN FRANCE: A COMPARISON WITH THE EUROPEAN RESULTS FROM THE IBIS-C OBSERVATIONAL STUDY

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OBJECTIVES: To describe the population of moderate-to-severe IBS-C patients in French clinical practice and to compare the main data with the European data from the IBIS-C study. The IBIS-C study was conducted in six European countries (France, Germany, Italy, Spain, Sweden and UK). **METHODS:** Observational, retrospective-prospective (6 months each) study of patients diagnosed (Rome-III criteria) in the last five years and moderate-to-severe IBS-C severity at inclusion (IBS-Symptom Severity Scale [IBS-SSS] score ≥175). Healthcare resource utilisation (HRU) was retrospectively and prospectively assessed and quality-of-life (QoL) was assessed at baseline with IBS-QoL and EuroQoL-5D (EQ-5D). **RESULTS:** Patient characteristics were similar between the French (n= 59) and European (n=525) cohorts: mean (±SD) age 47.7±15.7 and 45.3±15.8 years; 83% and 87% were female, and 63% and 60% had severe IBS-C. Mean symptom duration: 13.5±13.5 and 12.8±13.1 years; mean time since diagnosis: 2.6±6.3 and 3.0±5.2 years. At baseline, mean IBS-QoL was 42.9±19.0 and 54.9±22.7 (scale: 0-100[worst-best]); mean EQ-5D was 46.6±22.2 and 55.5±21.7 (scale: 0-100[worst-best]). Over follow-up, 76% French and 73% European patients consulted a GP (mean: 4.2 and 4.9 visits), and 100% and 92% a gastroenterologist (mean: 2.2 and 2.8 visits). 17% and 18% required emergency department visits/hospitalisation (mean stay: 6±6 and 14±24 days). 51% and 65% of patients took prescription drugs for their IBS-C, 61% and 67% took non-prescription drugs. Mean symptom severity (IBS-SSS) improved: 338.9±78.6 (baseline) to 281.5±102.1 (6 months) for the French cohort; 323.2±84.3 to 253.9±105.6 for the European cohort. The total mean (95%CI) annual cost for moderate-to-severe IBS-C was €4,128 (2,262-6,633) for the French cohort; €4,639 (3,733-5,598) for the European cohort. **CONCLUSIONS:** Moderate-to-severe IBS-C symptoms in France were similar to those other European countries. QoL impairment and HRU were high for both cohorts. Moderate-to-severe IBS-C continued to be a burden for both cohorts with a high economic cost despite availability of therapeutic interventions.

PGI57

MEDICAL RESOURCE UTILISATION OF AUSTRALIAN PATIENTS WITH GENOTYPE 1 CHRONIC HEPATITIS C: A RETROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: To understand medical resource utilisation (MRU) of Australian patients with genotype 1 chronic hepatitis C (GT1 CHC) including those receiving current standard of care treatment (telaprevir or boceprevir with pegylated interferon and ribavirin). **METHODS:** Medical records were reviewed for a stratified random sample of GT1 CHC patients first attending two liver clinics between 2011 and 2013 (principal population; PP) supplemented by all GT1 CHC patients attending one transplant clinic in the same period (transplant population; TP). CHC-related MRU (percentage and annual rate [poisson] of outpatient, hospitalisation, laboratory and imaging tests) is reported for the PP by treatment status (treated/not treated) stratified by fibrosis grade; and for TP pre-transplant, year of transplant and post-transplant. **RESULTS:** Comprehensive MRU was collected for 276 PP patients (F0-1 n=59, F2 n=58, F3 n=53, F4 n=106; 38 were treatment experienced prior to first visit; mean follow-up 17.6 months). Fifty-five (19.9%) received triple therapy. Data were collected for 112 TP patients (mean follow-up 29.9 months), 33 (29.5%) received a transplant during the study and 51 (45.5%) beforehand. MRU was higher while treated including annual rates of outpatient visits (PP: 9.67 vs 2.91 [F0-1 2.60, F2 2.56, F3 2.63, F4 3.33]; TP: transplant 18.00 vs pre 5.55, post 5.14), psychiatric visits (PP: 0.71 vs 0.18 [F0-1 0.25, F2 0.16, F3 0.20, F4 0.14]; TP: transplant 0.00 vs pre 0.50, post 0.01), nurse visits (PP: 1.84 vs 0.42 [F0-1 0.58, F2 0.42, F3 0.51, F4 0.32]); and the percentage with hospitalisation (PP: 27.3% vs 13.0% [F0-1 3.4%, F2 10.3%, F3 9.4%, F4 21.7%]; TP: transplant 100% vs pre 96.5%, post 79.2%). **CONCLUSIONS:** CHC-related MRU increases substantially with disease severity. To our knowledge, these are the first real-world MRU reported for GT1 CHC in Australia and will be valuable in assessing the impact of new hepatitis C treatments.

PGI58

HEALTH TECHNOLOGY ASSESSMENT IN CHRONIC HEPATITIS C: ASSESSMENT OF DECISION LANDSCAPE AND MANUFACTURER INPUTS IN SIX AGENCIES

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OBJECTIVES: To evaluate the landscape of health technology assessment (HTA) decisions for chronic hepatitis C (CHC) therapies in Canada (CADTH), Australia (PBAC), England and Wales (NICE), Scotland (SMC), Germany (IQWiG), and France (HAS). **METHODS:** Selected HTA agency websites were searched for submissions made in the CHC therapy area. Submissions were searched for following information: clinical and economic input provided in the submission, recommendations from HTA agencies, and drivers of HTA decisions. **RESULTS:** Victrelis®, Daklinza®, Roferon A®, Intron A®, Harvoni®, Viekirax®, Pegasys RBV®, PegIntron®, Rebetol®, Olysio®, Sovaldi®, and Incivo® were the pharmacotherapies for which manufacturer submissions were available across selected agencies. The number of HTA submissions with completion status ranged from 6-12. The percentage recommendation ranged from 43% in Australia to 100% in France and Canada. The number of clinical studies supporting the manufacturer submission ranged from 2-12. The